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(54) **Manufacture of a prosthetics socket**

(57) A jig for use in the manufacture of a prosthetics socket comprises an attachment ring (10) for attaching one end of the jig to a cup (62) shaped to fit onto the stump of an amputee, a connector (20) which can be adjustably fixed to the attachment ring (10), a number of bars (34) of different lengths each of which can be attached to the connector (20) at one end, and a clamp (44) for clamping a prosthetics attachment ring (64) in relation to the cup (62) and which is fixed to the end of one of the bars (34) which is further from the cup (62).

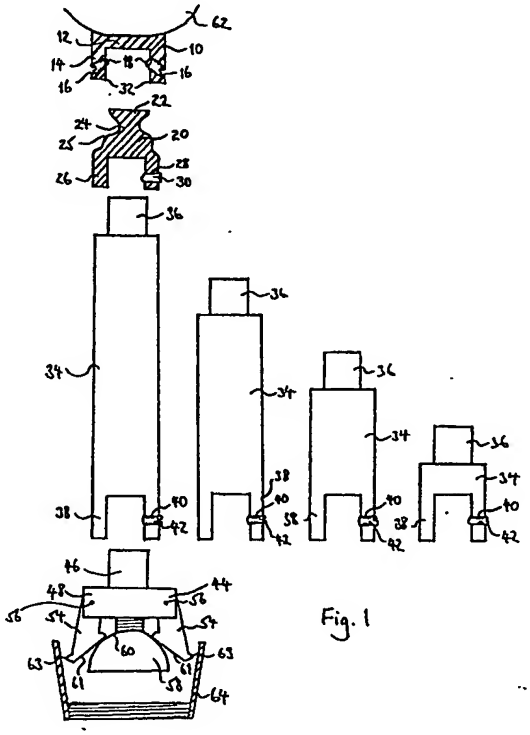

Fig. 1

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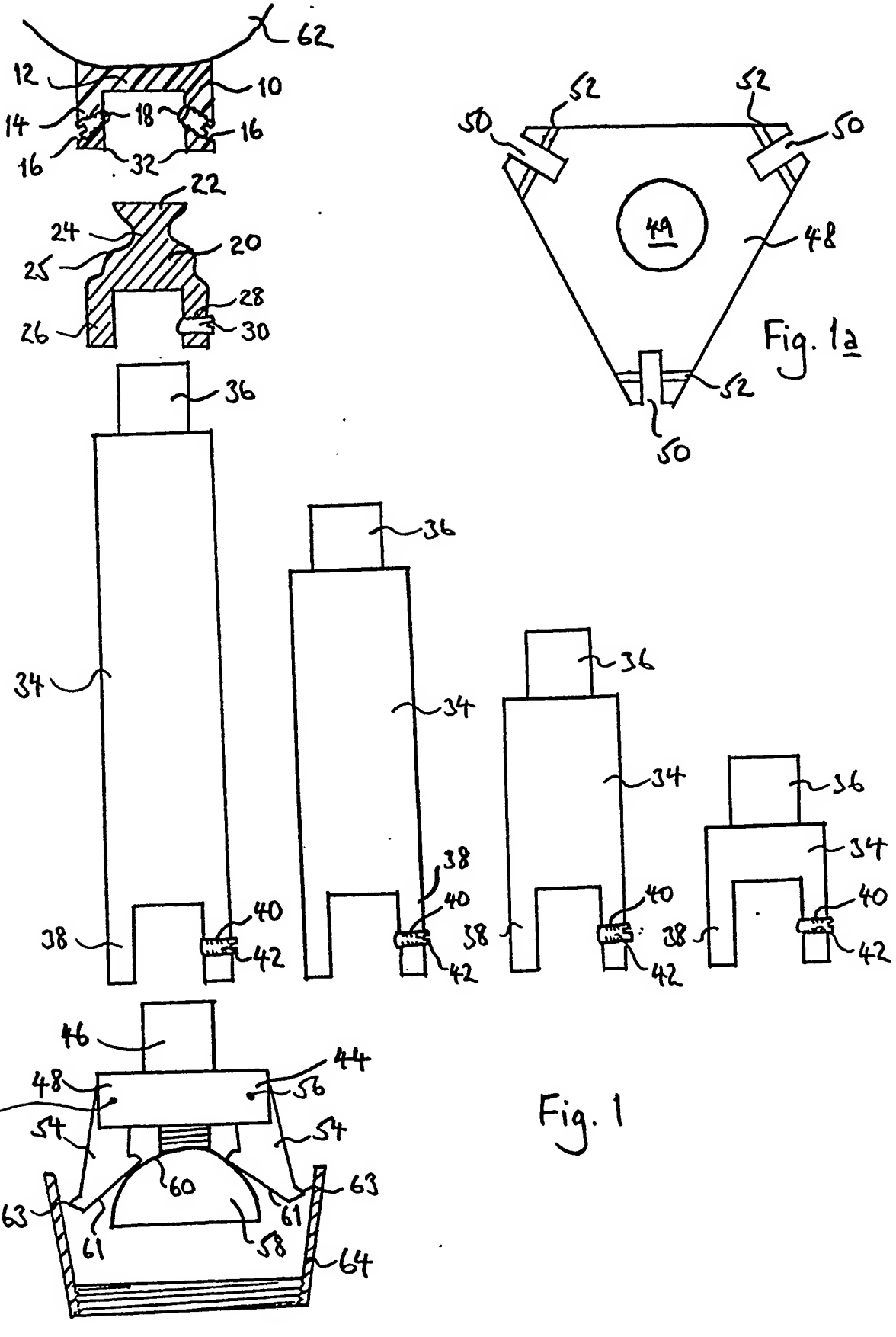
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Fig. 1

52
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Fig. 1a

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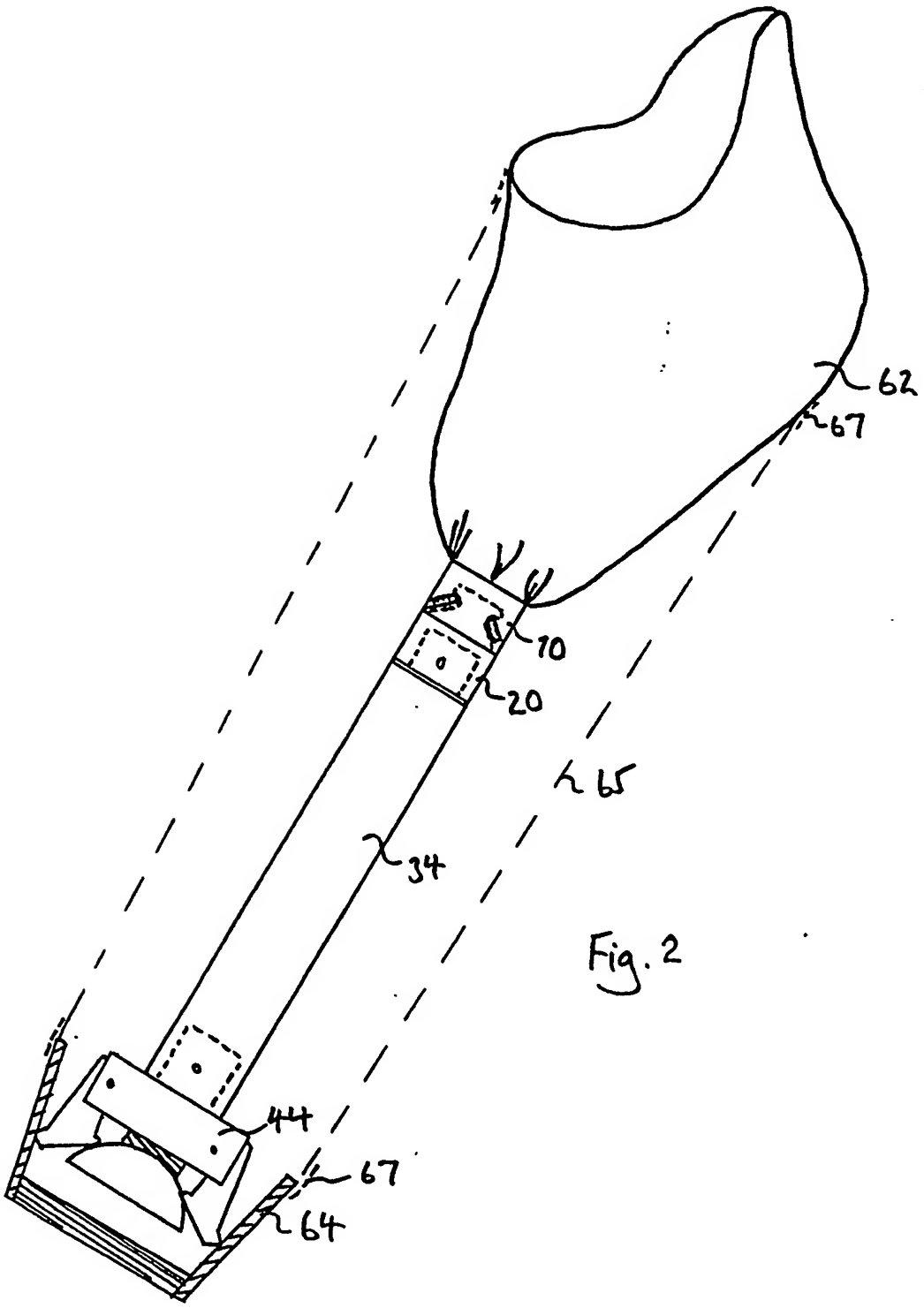

Fig. 2

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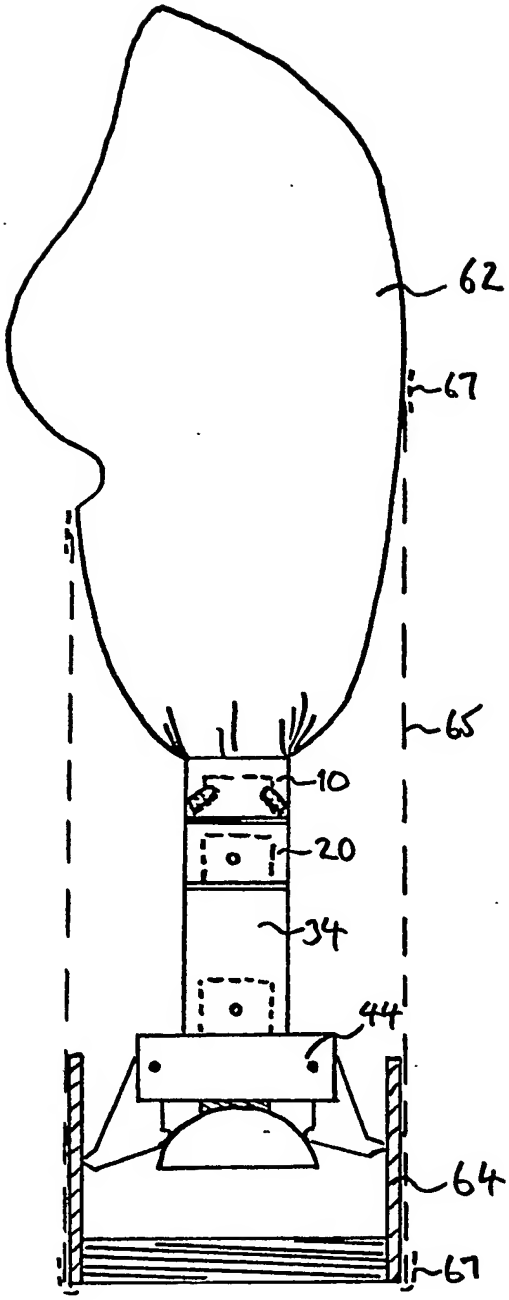

Fig. 3

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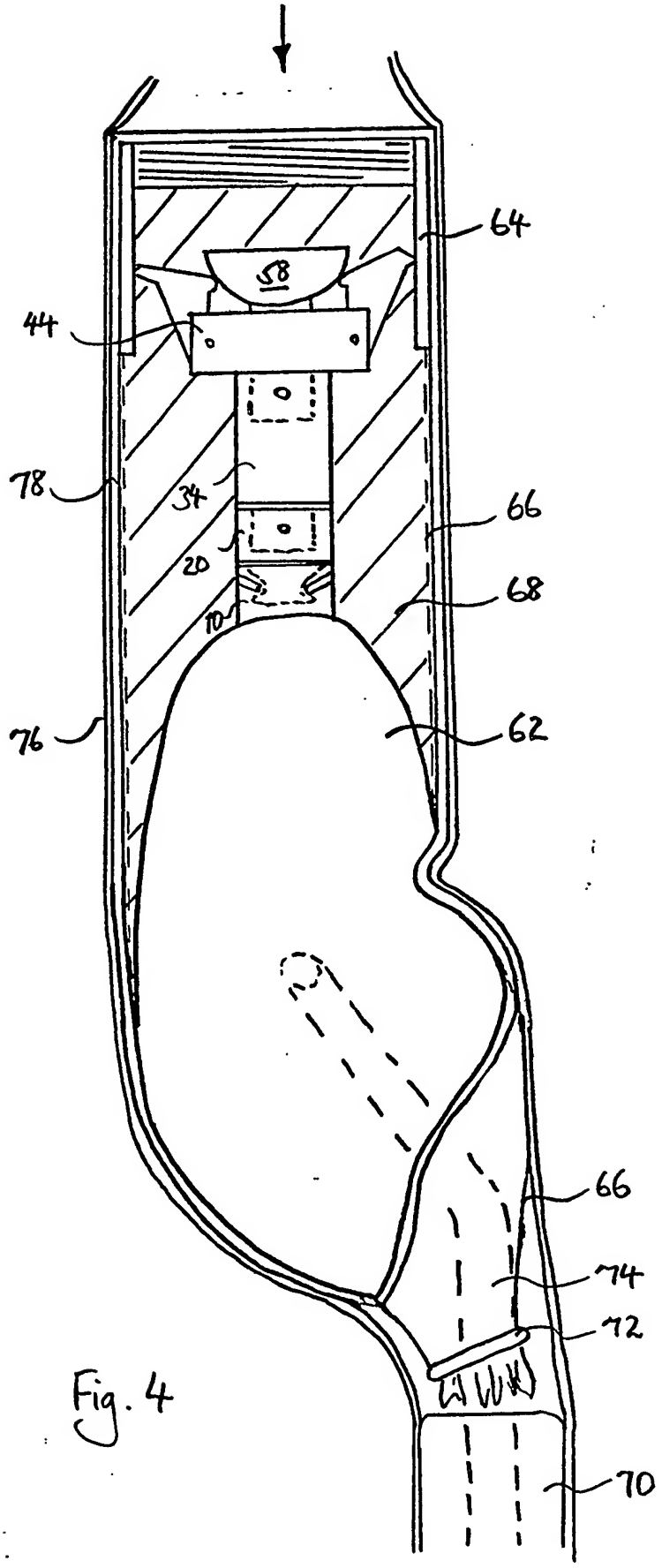

Fig. 4

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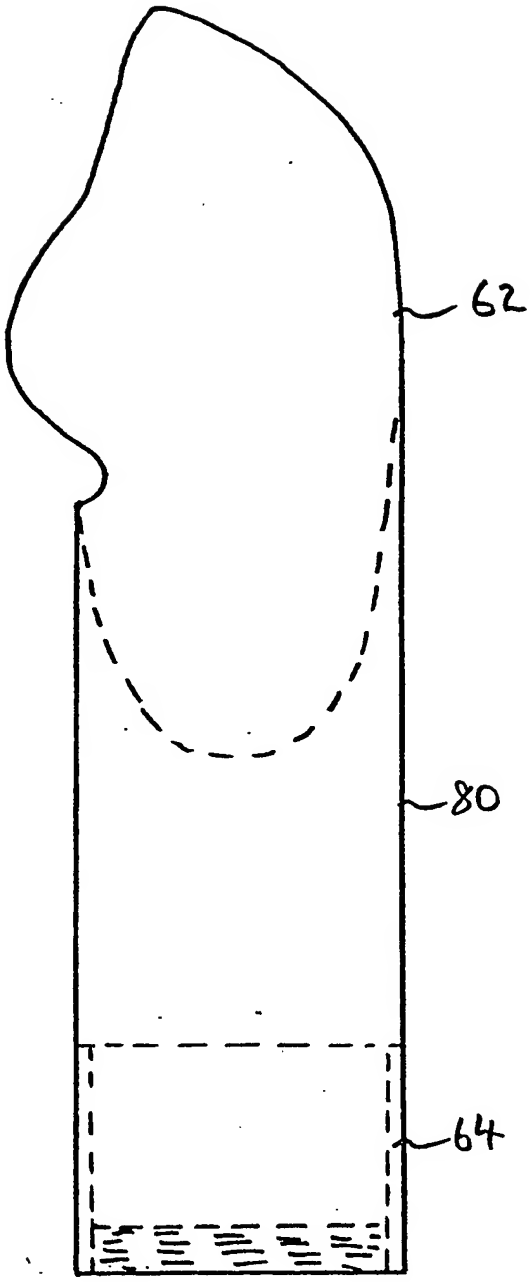

Fig. 5

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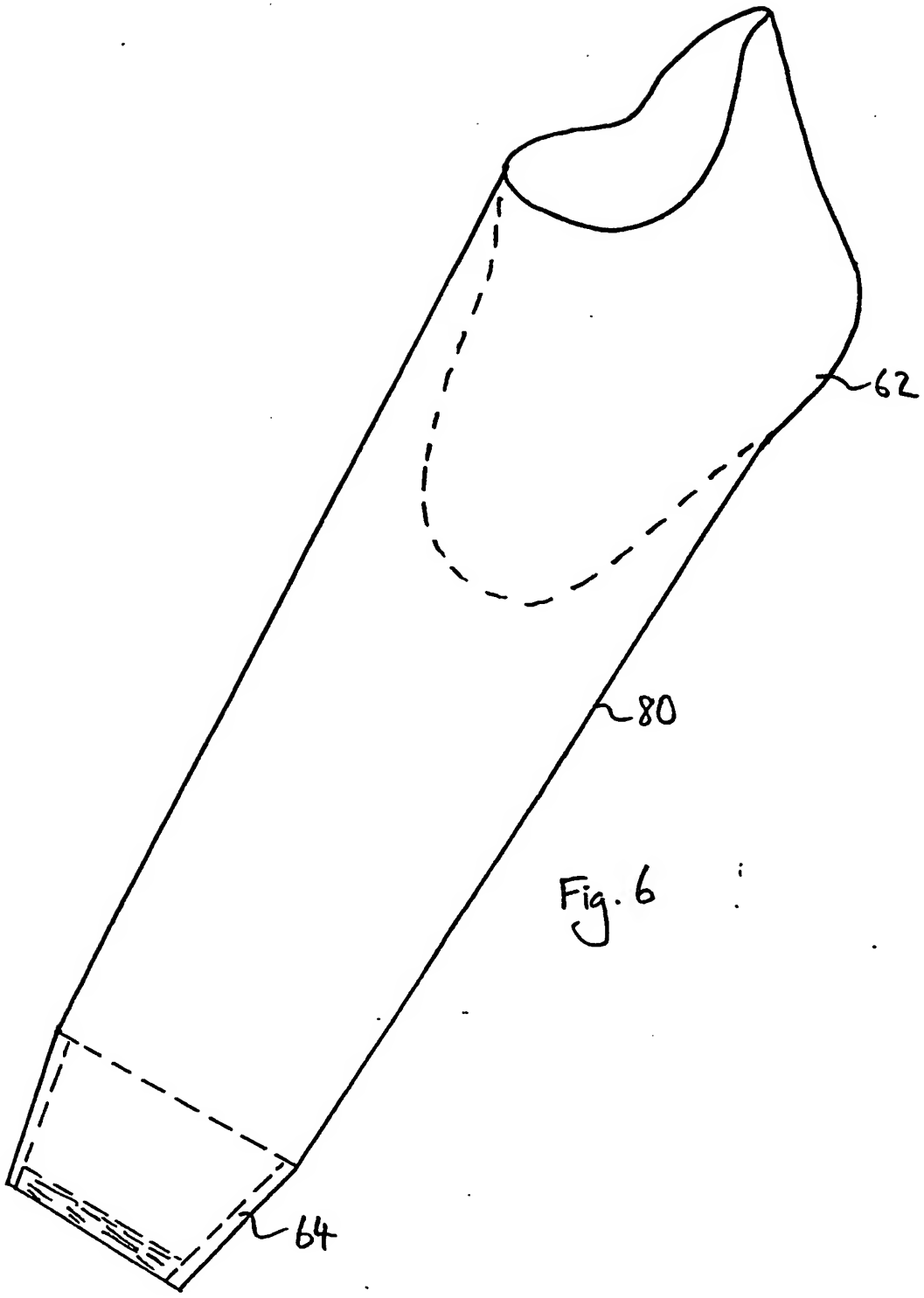

Fig. 6

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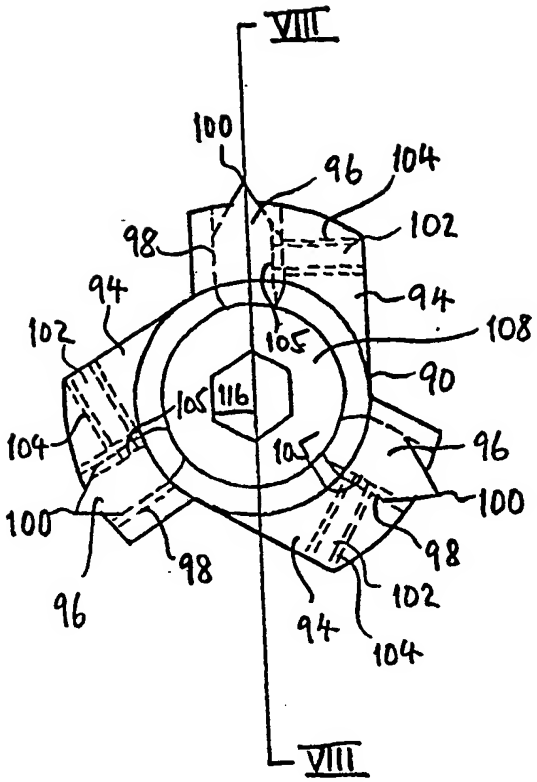

Fig. 7

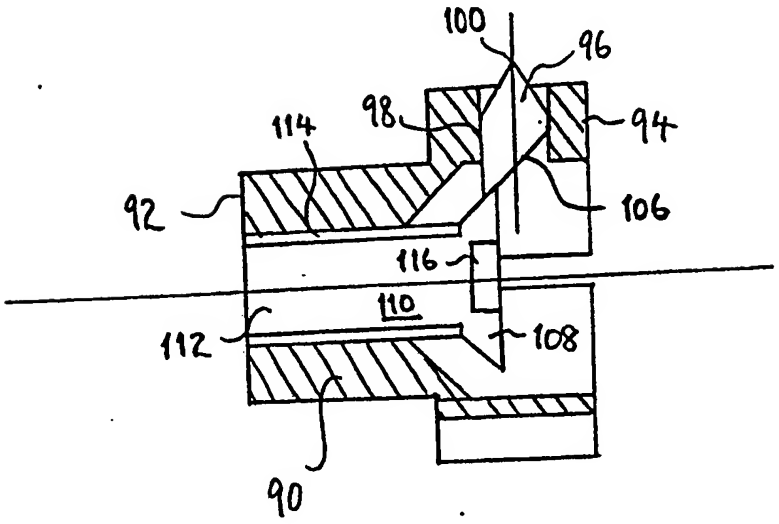

Fig. 8

SPECIFICATION

Manufacture of a pr sth tics socket

The present invention relates to the manufacture of a prosthetics socket.

One form of socket which provides a mount for an artificial arm or wrist comprises a cup portion, shaped to receive the patients' shoulder or elbow, a cylindrical portion attached at one of its ends to the cup portion, and a ring secured to the other end of the cylindrical portion. Attachment means are provided on the ring for securing the prosthesis to the socket. The cylindrical portion acts as the upper or lower portion of an arm and sets the ring in the current position in relation to the shoulder or elbow.

Hitherto, during the manufacture of such a socket, the ring has been correctly positioned in relation to the cup portion of the socket using a cylindrical plaster cast with the aid of a plumb line. Flesh-tinted plastics material has then been laminated onto the plaster cast to provide the cylindrical portion of the socket. Finally, the plaster cast has been removed from the interior of the plastics cylinder to leave the finished article.

With the introduction of new technical and advanced prosthetic components and procedures in artificial limbs, it is now apparent that a more positive technique is required to align and balance them during a fitting and testing stage prior to actual manufacture. This is necessary to ensure that critical alignments are not lost or altered during subsequent manufacture of the socket, and that when the socket and limb are eventually fitted, the amputee has optimal use and control of the limb.

An aim of the present invention is to meet this requirement. Accordingly, instead of using a rough judgement by eye, such as is made in the old plaster cast and plumb-line technique, a jig is provided having rigid components which are adjustable in relation to one another, whereby upper and lower portions of prosthetics socket can be initially set in the correct relative positioning. Once this is done, an intermediate portion of the socket can be formed between the upper and lower portions, securely attached to both. Preferably, the jig is so made or so fixed to the upper and lower portions that it can subsequently be removed.

An example of a jig in accordance with the present invention, and a method of making a prosthetics socket using such a jig, is illustrated in the accompanying drawings in which:–

Figure 1 is an exploded elevational part-sectional view of the jig, with interchangeable parts;

Figure 1*a* is a plan view of one part of the jig;

Figure 2 is an elevational view of the assembled jig holding upper and lower portions of a below-elbow socket;

Figur 3 is an elevational vi w of the assembled jig holding upper and lower portions of an above-elbow socket;

Figure 4 shows an elevational view f on stage in the making of the intermediate portion between upper and low r portions of a socket;

Figur 5 shows an elevational view of a finished above-elbow socket;

Figure 6 shows an elevational view of a finished below-elbow socket;

Figure 7 shows a diagrammatic plan view of a jig-part designed for the production of a child-size socket; and

Figure 8 is an axial sectional view of the jig-part taken in the plane VIII-VIII indicated in Figure 7.

The jig shown in Figure 1 includes a nylon attachment ring 10 having an upper wall 12 and an annular portion 14 through which extend four screw-threaded bores 16 (only two of which are illustrated) spaced apart around the annular portion 14. These slant from the outside of the annular upwardly towards the upper wall 12, and accommodate respective grub or Allen screws 18.

The next portion of the jig is a nylon tube connector 20 having a flat head or boss 22, a neck portion 24, a curved shoulder portion 25, and an annular part 26 through which a bore 28 extends for a locking grub or Allen screw 30. When the jig is assembled, the head 22 of the connector 20 is received in the annular portion 14 of the attachment ring 10. The distance between the flat top of the head 22 and the shoulder portion 25 is less than the depth of the annular portion 14 of the ring 10. This allows the connector 20 to be swivelled in relation to the ring 10 with the shoulder portion 25 always in contact with the inner edge 32 of the lower end of the ring 10 all the way round.

A third part of the jig is one of four interchangeable aluminium extension tubes or round bars 34. Each of these has a narrowed cylindrical end portion 36 so dimesioned as to fit into the annular part 26 of the tube connector 20. Each also has an annular portion 38 at its other end through which extends a screw-threaded bore 40 accommodating a locking grub or Allen screw 42. The lengths of the four interchangeable extension bars decreases in steps of 1 inch (25.4 mm) from one bar to the next. However, the overall length of the jig can be adjusted by increments of ¼ inch (6.4 mm) using short extension bars of ¼ inch (6.4 mm) and ½ inch (12.7 mm).

The lowermost part of the jig is a stainless steel expanding clamp 44. This has a cylindrical connecting portion 46 designed to fit into the annular portion 38 of any one of the extension bars 34. The connecting portion 46 extends upwardly from the centre of a triangular mounting flange 48. Extending centrally through the flange 48 is a screw-threaded hole 49, as shown more clearly in Figure 1*a*. Three slots 50 extend inwardly from the three corners of the flange 48, and narrow pin-receiving bores 52 extend across the corners and the slots 50. Respective claws 54 are mounted on the flange 48 with their upper ends pivotally secured by m ans of pins 56 extending through the bores 52. A large but r latively short bolt 58 ngages the screw-threaded h le 49. Its h ad has an inwardly facing hemispherical undersid

The drawing(s) originally filed was/were informal and the print here reproduced is tak n from a later filed formal copy.

against which rest slanting lower edges 61 of the claws 54. The lower outer ends 63 of the claws 54 are pointed for effecting outward clamping. The outer face of the head of the bolt 58 is mainly flat, but has a shaped recess for receiving the end of a tool, such as a screw-driver or radiator key, to allow the bolt to be rotated in relation to the flange 48.

When the jig is used in the production of an artificial-limb socket, the attachment ring 10 is first fixed onto the lower or distal end of a flesh-tinted plastics cup portion 62 for the socket. If the finished socket is to act as an artificial lower portion of the arm, the cup portion is shaped to receive the below-elbow stump, which may extend around the elbow joint as shown in Figure 2, in which case the cup portion is referred to as a munster. If the finished socket is to act as an artificial upper portion of the arm, the cup portion is shaped to receive the above-elbow stump, which may extend around the shoulder joint as shown in Figure 3. Plasticine is used to initially position the ring 10 on the cup portion 62 with the four Allen screws 18 in medial, lateral, anterior and posterior positions respectively. A wooden spatula is then used to apply Otto Bock Acrylspachtel paste all around the join between the ring 10 and the socket 62. Once the paste has hardened, the plasticine is removed.

The jig may now be assembled by inserting the head 22 of the connector 20 into the ring 10, the narrowed end 36 of one of the bars 34 into the annular part 26 of the connector 20, and the connecting portion 46 of the expanding clamp 44 into the annular portion 38 of the bar 34, the various Allen screws being used to secure the pieces together.

Finally, a knurled and internally screw-threaded aluminium or other metal ring 64 is positioned around the expanding clamp 44. For a below-elbow socket, the ring 64 is tapered or parallel and acts as a housing when in use, either at the wrist position or further up the forearm in the case of a mid-forearm bi-section. The bolt 58 is screwed further into the flange 48 to urge the claws 54 to pivot outwardly about the pins 56. The pointed ends 63 of the claws dig into the inner surface of the ring 64 to fix the latter firmly in position in relation to the jig and the cup portion 62 for the socket.

Assembly of the jig is now complete. An assembly for a below-elbow socket is shown in Figure 2, and one for an above elbow socket is shown in Figure 3. To ensure correct balance and alignment, the assembly is fitted onto the patient and the prosthesis, which may comprise an elbow joint, lower arm portion, wrist and hand for a below-elbow socket, is screwed into the housing ring. The patient may now test out operation of the prosthesis, adjustments being made to the jig until correct balance and alignment is achieved to give the patient optimum use of the prosthesis. The following adjustments are possible:

(a) swivelling of the connector 20 in relation to the ring 10 in any direction by manipulation of the four Allen screws 18;

(b) rotation of the connector 20 in the ring 10 by slackening the screws 18, rotating the connector 20, and then re-tightening the screws 18;

(c) rotation of bar 34 in relation to the connector 20;

(d) rotation of the clamp 44 in relation to the bar 34;

(e) a coarse adjustment in length by replacing the bar 34 by another one of different length;

(f) a fine adjustment in length by loosening the clamp 44, moving the ring 64 up or down in relation to the clamp, and then tightening the latter again;

(g) after loosening the clamp, it is also possible to rotate the ring 64 in relation thereto, to ensure that the prosthesis joint moves in the correct plane (although adjustments (b) (c) and (d) could also be used to do this);

(h) finally, again after loosening the clamp, it is possible to swivel or skew the ring 64 in relation thereto in any direction, to obtain correct angular alignment of the prosthesis. This is facilitated by having only three claws 54 on the clamp 44.

Having used one or more of these means of adjustment to position the ring 64 in the precisely correct position in relation to the cup portion 62 for the socket, to achieve correct balance and alignment of the prosthesis in relation to the patient, the assembly can be removed from the patient and transferred to the workshop with the jig *in situ*. In this way, no misalignment or inbalance can be introduced accidentally between the fitting stage and completion of production.

At the workshop, a thin stiff sheet of plastics material 65, preferably ester coated as in the case of X-ray film, is wound around the jig assembly to form a cylinder extending between the cup portion 62 and the ring 64. The ends of the cylinder are sealed against the cup portion 62 and ring 64 using adhesive tape 67. With the whole assembly inverted, melted paraffin wax is poured into its interior. When the wax has cooled and hardened, the plastics sheet is removed.

As shown in Figure 4, in the case of the production of an above-elbow socket, nylon stockinette material 66 is pulled over the whole assembly, including the solidified wax 68, up to eight layers thick. This is achieved either by pulling one long stockinette over itself a number of times, or by applying eight short stockinettes separately on top of one another. This assembly is positioned inverted and adjacent to a vacuum unit intake taube 70. The proximal end of the stockinette material 66 is tied at 72 to a bent rod 74 which extends into the intake tube 70 at one end and the cup portion 62 at the other. An appropriately shaped P.V.A. sleeve or bag 76 is then slipped over the whole arrangement, from the distal end of the jig assembly to the intake tube 70 of the vacuum unit (not shown). A flesh-tinted plastics resin 78 is then poured in as indicated by the arrow at the top of Figure 4. The resin 78 flows around the outside of the jig assembly underneath the sleeve 76 so that it impregnates the stockinette material 66. The upper end of the sleeve 76 is then closed. As a result, when the vacuum unit is operated, the sleeve 76 is evacuated to ensure that the impregnation is thorough and uniform, and that the resulting impregnated stockinette material conforms closely to the outsides of the knurled ring 64, the solidified wax 68, and the

cup portion 62. In this way, a plastics resin laminate is formed around the wax 68.

7Th assembly is now r moved from th vacuum unit intak tube 70, and plac d in an oven (not shown) until the paraffin wax has melted and drained out and the plastics resin has been fully cured. Surplus wax on the distal end of the knurled ring 64 may have to be removed to allow complete draining.

On removing the assembly from the oven, the bolt 58 is unscrewed to release the hold of the expanding damp 44 on the ring 64. Since the Acrylspachtel paste between the attachment ring 10 and the cup portion 62 becomes soft when hot, the whole jig should be removable as one piece from the interior of the completed socket. If it is not, however, a small hole (not shown) can be drilled through the cured resin opposite the Allen screw which secures the upper end of the extension bar 34. A ball driver may then be inserted through that hole and used to slacken the Allen screw so that the bar 34 with the clamp 44 can drop out. The hole may be left as a ventilation hole or filled with a mixture of Degaplast and pigment paste.

A finished above-elbow socket is shown in Figure 5, and a finished below-elbow socket is shown in Figure 6. Each comprises a flesh-tinted plastics cup portion 62, a flesh-tinted plastics cylindrical portion 80 bonded to the cup portion at its upper end, and an internally screw-threaded aluminium ring 64 surrounded by and bonded to the other end of the cylindrical portion 80. The cylindrical portion 80 is constituted by the resin which was cured while the whole assambly was in the oven.

In the event that the cup portion 64 and ring 62 have to be set relatively close to one another, the connector 20 and bar 34 may have to be omitted from the jig assembly. In this case, the attachment ring 10 has to be positioned accurately on the cup portion 62, and the connecting portion 46 of the clamp 44 is inserted directly into the ring 10. The possible means of adjustment are then a slight medial/lateral and anterior/posterior movement of the clamp 44 in relation to the ring 10 by manipulation of the Allen screws 18, rotation of the clamp 44 in relation to the ring 10, and longitudinal, skew, and rotational movement of the ring 64 in relation to the clamp 44.

If a socket is required for a child to use, the expanding clamp 44 may be too large to fit into an appropriately sized ring 64. A different form of expanding clamp would then be used, such as that illustrated in Figures 7 and 8.

In this clamp, a main stainless steel block 90 has a cylindrical portion 92 with an exteranl cross-sectional diameter slightly smaller than the internal cross-sectional diameter of a flange portion 38 of an extension bar 34 shown in Figure 1, to allow the clamp to be secured to any one f the extension bars in the same way as the clamp 44. Three flange portions 94 of the block 90 project radially outwardly from a lower end thereof with 120° spacings between them. Respective pointed pins 96 fit snugly in radially extending bores 98 through th flange portions 94, the points 100 of the pins projecting outwardly beyond the ends of the flange portions 94. The pins 96 are able to slide axially along the bores 98, but can be secured in any position in relation thereto by three 6BA × ¼" (6.4 mm) long full dog point socket headed grub screws 102 which extend tangentially of the block 90 through respectively screw-threaded bores 104 in the flange portions 94. The grub screws 102 engage flats 105 formed along the sides of the pins 96.

The inside ends of the pins 96 have slanting faces 106 sloping towards the cylindrical portion 92 of the block 90. These slanting faces 106 are engaged by the underside of a head 108 of a standard countersunk main screw 110, the head 108 tapering towards the shank 112 of the screw 110. The shank engages an internally screw-threaded bore 114 extending axially through the cylindrical postion 92 of the block 90. A hexagonal recess 116 in the head 108 of the screw 110 allows it to be adjusted by means of a hexagonally cross-sectional radiator key (not shown), although it will be appreciated that other shapes or forms of recess and key could be used.

To adjust the overall radial dimensions of the clamp, on securing a ring 64 thereto, the grub screws 102 are slackened and the main screw 110 is rotated to move it inwardly or outwardly along the axis of the clamp. If the main screw 110 is moved inwardly, the pins 96 are pushed outwards as the slanting faces 106 and the head 108 slide against one another. This allows a gradual adjustment. If the pins 96 are pushed out too far, the main screw 110 is moved outwardly and the pins 96 are pushed back in to re-establish contact between the faces 106 and the head 108. Once the pins 96 are set in the right position in relation to the block 90, the grub screws 102 are re-tightened.

This modified form of clamp may be made in more than one size to make up a full set of interchangeable components.

CLAIMS

1. A jig for use in the manufacture of a prosthetics socket, comprising attachment means at one end of the jig for attaching that end to a cup shaped to fit onto the stump of an amputee, and a clamp at an opposite end of the jig adapted to clamp a prosthetics attachment ring to the jig.

2. A jig according to claim 1, in which the attachment means are adjustable in relation to the cup when the jig is in use.

3. A jig according to claim 2, in which the attachment means comprise an attachment ring which can be fixed to such a cup by means of adhesive, a plurality of screws or other fixing elements which extend through and engage in holes in the ring, the holes slanting inwardly and towards that side of the ring which is intended to be fixed to such a cup, and a connecting member having a neck portion and a head portion adapted to fit into the attachment ring and to be adjustably secured thereto by displacement of the fixing lements in relation to the attachm nt ring inwardly towards the head portion.

4. A jig according to any preceding claim, in which the clamp comprises two parts which are movable relative to one anoth r, and claws held by

on of these parts and arrang d to be urg d outwardly as the two parts are moved relative to one another.

5. A jig according to claim 4, in which the said two parts comprise a bolt and a part which is fixed when the jig is in use, the bolt engaging an internal screwthread in the fixed part.

6. A jig according to claim 5, in which the bolt has a head which is substantially hemispherical on the side from which the shank extends, and in which the claws are pivoted from the fixed member and are in contact, when the jig is in use, with the hemispherical surface so that they are pivoted outwardly when the bolt is screwed further into the fixed part.

7. A jig according to claim 5, in which the claws extend and are slidable within radially extending holes or recesses in the fixed part, the inside ends of the claws and/or the side of the bolt head from which the shank extends slanting so that, when the bolt is screwed further into the fixed part, the claws are moved outwardly.

8. A jig according to any preceding claim, in combination with a number of bars of different length, the ends of each of which are constructed to allow the attachment means and the clamp to be fastened thereto.

9. A jig for use in the manufacture of prosthetics socket, substantially as described herein with reference to Figures 1 to 4, or to Figures 1 to 4 modified in accordance with Figures 7 and 8 of the accompanying drawings.

10. A jig assembly for use in the manufacture of a prosthetics socket, comprising a jig as claimed in any preceding claim having its attachment means attached to a cup shaped to fit onto the stump of an amputee, and its clamp fixing a prosthetic attachment ring in relation to the cup.

11. A method of making a prosthetics socket, in which a prosthetics attachment ring is fixed in relation to a cup shaped to fit onto the stump of an amputee, by means of a jig as claimed in any preceding claim.

12. A method according to claim 11, in which a cylinder is arranged to extend between the cup and the ring, and the cylinder is filled with a material which melts easily but which is solid at room temperatures, such as paraffin wax, to form a base onto which a cylindrical portion of the prosthetics socket may be formed.

13. A method according to claim 12, in which the solid cylinder is surrounded by stockinette material or other impregnatable material, the impregnatable material is impregnated with a plastics resin, and the whole assembly is heated to melt the solid cylinder and cure the plastics resin.

14. A method according to claim 13, in which the impregnatable material is surrounded by a further layer, the plastics resin is poured into regions between this further lay r and the impregnatable material, and the resin is urged into th impr gnatabl mat rial by drawing air from the interior of the further layer.

15. A method according to any one of claims 11 to 14 and substantially as described her in with reference to Figur 4 of the accompanying drawings.

16. A prosthetics socket made by a method according to any one of claims 11 t 15.

17. A prosthetics socket according to claim 16 and substatially as described herein with reference to Figures 5 or 6 of the accompanying drawings.

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